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10/567,120	09/28/2007	Hans Gregersen	030307-0279	2999

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EXAMINER	
STOUT, MICHAEL C	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,120	GREGERSEN ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/3/2006,09/28/2007,03/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/567120 filed on 9/28/2007 and is a first action based on the merits of the application. IDS document(s) filed on 2/03/2006, 09/28/2007 and 3/22/2008 is/are being considered by the examiner.

Claims filed on 2/03/2006 are currently being considered. Claims 36-70 are currently pending.

Information Disclosure Statement

The information disclosure statement filed 9/28/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The disclosure is objected to because of the following informalities: Page 9 line 15 refers to Figure 3, however the following description is in reference to parts of Figure 3A.

Appropriate correction is required.

Claim Objections

Claim 37 is objected to because of the following informalities: Claim 37 recites in line 3 the limitation of "wherein other at least…" appears as though it should read "wherein *the* other at least...". Appropriate correction is required.

35 USC § 112 6th Paragraph

Claims 36, 37, 40, 46, 47 and 48 recite means plus function limitations in the claims which properly invokes 112 6th paragraph as set forth in MPEP 2181, and the claims have been examined under procedure set forth therein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-48, 64-66 and 68-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 37, 40, 46, 47 and 48 recite means plus function limitations wherein the specification does not identify structure or functional equivalents for performing the function. Therefore the scope of the claim is unclear because one skilled in the art

would not be able to identify what structure or functional equivalents are encompassed by the claim.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Regarding claims 44, 45, 54 and 55, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 41, 42, 54 and 55 recites the limitation "the more than two electrodes" in claims 36 and 49. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 and 50 recite the limitation of comprising four or more electrodes, it is unclear whether the four or more electrodes is a further limitation of the at least two or more electrodes comprising at least four electrodes or is in reference to an additional four electrodes in addition to the two or more electrodes.

Regarding claim 46, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 44, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 37 recites the limitation when passing electrical current to an outer surface of the probe, the outer surface abutting an inner wall…, it is inclear what structure passes current to the outer surface. Furthermore, it is unclear what is being claimed as the limitation is an incomplete statement. The limitation is drawn to function of the device stating: when passing current ….. ?

Claim 67 is an apparatus claim dependant upon a method claim and it is unclear whether the claim is drawn to a method or apparatus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 36 and 70 positively recites the limitation of the probe comprising a conducting medium attached to the probe. The disclosure teaches the elastic probe being attached to the body. Thus the limitation of a conducting medium attached to the probe includes components of the human body which is non-statutory subject matter.

Claim 67 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, because the claim is directed towards two statutory categories. Claim 67 is a dependant claim of 49 which is a method; however claim 67 is directed to an apparatus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-38, 41-44, 46, 48, 49-51, 54-59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1).

Regarding claim 36, Greco teaches inter alia an apparatus for measuring the deformation of a system, the apparatus comprising: - an elongated elastic probe (catheter system 5, see Figure 1 and Figure 2, and [0004] and [0042]), - a conducting medium attached to or contained by the probe (saline solution 50 passing through a channel for to the inside of the balloon 20, [0004]), and - two or more electrodes being electrically connected by the conducting medium(electrodes 80a-80d), the electrodes being attached to the probe (see Figure 1), wherein the apparatus furthermore comprising means for measuring an electrical parameter between at least two of the number of electrodes (electrical connectors 9 connect the sensors to external recording and/or analysis equipment, see [0004]), the measured electrical parameter being indicative of a deformation of the probe in at least the longitudinal direction of the elongated probe (the impedance measurements of the change in electrical properties of the fluid in the balloon in a longitudinal direction pressing against a lumen wall, see [0004]-[0005]).

Regarding claim 37, Greco teaches an apparatus according to claim 36 comprising four or more electrodes (80a-80d), wherein at least two of the four or more electrodes are measuring electrodes comprising means for measuring the electrical potential between them (sensing electrodes 80B and 80D and external recording/analysis equipment), and wherein other at least two of the four or more electrodes are generating electrodes (a high frequency alternating current is applied between excitation electrodes 80a and 80D, see [0005]) comprising means for generating an AC-field between the measuring electrodes.

Regarding claim 38, Greco teaches the apparatus according to claim 36, wherein the measured electrical parameter is indicative of a force of a certain magnitude being applied to the probe (the measured electrical properties of the fluid inside the balloon are indicative of force applied to the outside of the balloon, see at least [0003]).

Regarding claims 41 and 42, Greco teaches the apparatus according to claim 36, wherein the more than two electrodes are placed along a reference curve of the probe, where the reference curve is a longitudinal axis extending along the elongation of the elongate probe (as best shown in Figure 1 the four electrodes 80a-80d are positioned along the longitudinal axis of the device around the inner surface of the device inside the balloon), and thereby the more than two electrodes are placed along the longitudinal axis.

Regarding claims 43 and 44, Greco teaches the apparatus according to claim 36, wherein the conducting medium is a liquid medium serving as an electrolyte for

conducting the electric current between the electrodes, wherein the liquid medium is a liquid preferably non-harmful to the bodily hollow system or the engineered structure being stimulated, such as an acid like HCl in the stomach, or such as bile salts in the small intestine, or such as water with NaCl in the esophagus (saline solution 50, see [0004]-[0006]).

Regarding claim 46, Greco teaches the apparatus according to claim 36, further comprising at least one inflatable balloon situated between a proximal end and a distal end of the probe (See Figures 1 and 2), and the apparatus comprising means for passing an inflating fluid (channel 40, see [0004], preferably a liquid (saline), from the

proximal end to the balloon (see Figure 1), and where the apparatus optionally is provided with means for measuring at least one physical properties of the balloon (pressure/temperature sensors, see [0004]-[0006], see also [0042]).

Regarding claim 48, Greco teaches the apparatus according to claim 36, further comprising means for passing an electrical current through a number of wires in a number of the canals inside the probe (electrical connector 9 for passing a current though a number of wires in the probe lumen), and when passing the electrical current to an outer surface of the probe, the outer surface being a surface abutting the inner wall of the hollow system (the probe placed in a lumen).

Regarding claim 64, Greco teaches the apparatus according to claim 36 for use of subjecting a number of artificially applied stimuli to a bodily hollow system of a person or an animal, the stimuli being any of the stimuli: mechanical stimulus, thermal stimulus, chemical stimulus and electricstimulus (the device is capable of applying a number of artificial stimuli, see [0047], see [0004]-[0006] limitations drawn to the intended use of the device).

Regarding claim 65, Greco teaches the apparatus according to claim 36 for performing measurements in part of the digestive system including the stomach, preferably performing measurements in the gastrointestinal tract based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the gastrointestinal track in response to a stimuli, see [0047], see [0004]-[0006] limitations drawn to the intended use of the device).

Regarding claim 66, Greco teaches the apparatus according to claim 36 for performing measurements in part of the urogenital system of a person or an animal, the urogenital system including the urinary bladder based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the urogential system in response to a stimuli, see [0047], limitations drawn to the intended use of the device).

Regarding claim 67, Greco teaches the apparatus according to claim 49(36) for performing measurements in part of the cardiovascular system of a person or an animal, the cardiovascular system including the heart and the lymph system, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of measurements in the cardiovascular system in response to a stimuli, see [0047], limitations drawn to the intended use of the device)..

Regarding claim 68, Greco teaches the apparatus according to claim 36 for performing measurements in part of the tissue of a person or an animal, the tissue including epitheliuous tissue, connective tissue, skin, and adipose tissue, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of performing measurements in the tissue of a person, see [0047] limitations drawn to the intended use of the device).

Regarding claim 69, Greco teaches the apparatus according to claim 36 for performing measurements in part of the motoric system of a person or an animal, the

motoric system including the muscles and the bones, based on a prior stimulation of any of the following kinds: mechanical stimulus, thermal stimulus, chemical stimulus and electric stimulus (the device is capable of performing measurements in the tissue of a person, see [0047] limitations drawn to the intended use of the device).

Regarding claim 70, Greco teaches the apparatus according to claim 36 for performing measurement in non-human and non-animal systems such as in plants and in engineered structures.

Regarding claim 49, Greco teaches a method for measuring a deformation of a system by introducing into the system an elongated elastic probe (catheter system 5, see Figures 1 and 2, and [0004] and [0042]), the probe comprising: - a conducting medium attached to or contained by the probe, and - two or more electrodes being electrically connected by the conducting medium (saline solution 50 passing through a channel for to the inside of the balloon 20, [0004]), the electrodes being attached to the probe (electrodes 80a-80d), wherein a deformation being indicative of a deformation of the probe in at least the longitudinal direction of the elongated probe is measured by measuring an electrical parameter between at least two of the two or more electrodes (the impedance measurements of the change in electrical properties of the fluid in the balloon in a longitudinal direction pressing against a lumen wall, see [0004]-[0005]).

Regarding claim 50, Greco teaches the method according to claim 49, comprising four or more electrodes (80a-80d), wherein at least two of the four or more electrodes are generating electrodes generating an AC-field between (a high frequency alternating current is applied between excitation electrodes 80a and 80D, see [0005]) at

least two other electrodes being measuring electrodes (sensing electrodes 80B and 80D and external recording/analysis equipment), the measuring electrodes measuring the electrical potential between them.

Regarding claim 51, Greco teaches the method according to claim 49, wherein the deformation of the probe is indicative of a force of a certain magnitude being applied to the probe (see at least [0003]).

Regarding claims 54 and 55, Greco teaches the method according to claim 49, wherein the more than two electrodes are placed along a reference curve of the probe, and wherein the physical quantities, such as the forces, the distances, the acceleration or the speed deduced from at least the measured electrical parameter between at least two electrodes, are quantities measured along a direction defined by the reference curve, wherein the reference curve is a longitudinal axis extending along the elongate probe, thereby the physical quantities measured between the at least two electrodes are quantities along a substantial longitudinal extension of the probe (as best shown in Figure 1 the four electrodes 80a-80d are positioned along the longitudinal axis of the device around the inner surface of the device inside the balloon, see [0003]-[0006]).

Regarding claims 56, Greco teaches the method according to claim 49, wherein the probe is being provided with at least one inflatable balloon situated between a proximal end and a distal end of the probe (see Figures 1 and 2), and where the method comprises the further step of inflating the at least one balloon, until the balloon abuts an inner wall of the system in order for the balloon and the probe to be fixed longitudinally in relation to the system (see [0002]-[0006]).

Regarding claims 57, Greco teaches the method according to claim 56, wherein the measuring of the electrical parameter between at least two of the two or more electrodes is obtain in correlation with a pressure change inside the balloon, a volume change of the balloon, a determination of the cross-sectional area of the balloon or other changes of the balloon (See [0002]-[0006]).

Regarding claims 58, Greco teaches the method according to claim 56, wherein the measuring of the electrical parameter between at least two of the two or more electrodes is obtain in correlation with a wall change of the system surroundings of the probe (See [0002]-[0006]).

Regarding claims 63, Greco teaches the method according to claim 49, wherein the method is performed anywhere in one of the following bodily systems: the muscles, the connective tissue, the skin, the bones, or where the method is performed anywhere in one of the following bodily hollow systems: the digestive system including the stomach, the urogenital tract including the bladder, the cardiovascular system including the heart, the lymph system, the ear canal including the eustachian canal and the posterior nares ([0002]-[0006] and [0047]).

Claims 39 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Mortesen et al. "A system for measurements of micturition urethra cross-sectional areas and pressures." Med and Bio Eng and Computing July 1983.

Regarding claim 39, Greco teaches the apparatus according to claim 38 as set forth above wherein the deformation of the balloon the abutting outer lumen is determined from the measured electrical properties [0003]-[0006].

Greco is silent regarding wherein the force or the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function.

Mortesen teaches an elastic probe apparatus wherein the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function, see at least Figure 3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include a calibration function as taught by Mortesen in order to calibrate the device to provide quantitative measurements (i.e. diameter or length) which correspond to the electrical values sensed by the electrode measuring means, for example conversion factor/fucntion from voltage/impedance to mm.

Regarding claim 52, Greco teaches the method according to claim 51 as set forth above wherein the deformation of the balloon the abutting outer lumen is determined from the measured electrical properties [0003]-[0006].

Greco is silent regarding wherein the force or the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function.

Mortesen teaches a method of monitoring deformation wherein the deformation is deduced from the measured electrical parameter by means of a pre-determined calibration function, see at least Figure 3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include a calibration function as taught by Mortesen in order to calibrate the device to provide quantitative measurements (i.e. diameter or length) which correspond to the electrical values sensed by the electrode measuring means, for example conversion factor/fucntion from voltage/impedance to mm.

Claims 40 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Laege Gunnar Lose "Simultaneous Recording of Pressure and Cross-Sectional Area in the Female Urethra: A study of Urethral Closure Function in Healthy and Stress Incontinent Women" Neurourology and Urodynamics 11:55-89 (1992).

Regarding claim 40, Greco teaches the apparatus of claim 36 as set forth above. Greco is silent regarding the apparatus wherein the apparatus further comprising timer means for determining a timing of a change of the measured electrical parameter.

Lose teaches a deformation monitoring apparatus wherein the apparatus further comprising timer means for determining a timing of a change of the measured electrical parameter, see page 65 and 66 (Figure 4).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include a timer means as taught by Lose in order to monitor temporal changes in the measurements to correlate them with specific physiological events on measurements from other sensors.

Regarding claim 53, Greco teaches the method of claim 49 as set forth above. Greco is silent regarding, wherein a timing of a change of the measured electrical parameter is being determined, so as to obtain a measurement of a velocity and/or an acceleration of the deformation of the probe.

Lose teaches a deformation monitoring method wherein a timing of a change of the measured electrical parameter is being determined, so as to obtain a measurement of a velocity and/or an acceleration of the deformation of the probe (see page 65 and 66 (Figure 4) which shows a plot of the change size over time providing a slope indicating the velocity of the change).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include temporal

tracking means as taught by Lose in order to provide an indication of the rate of change of the monitored condition.

Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Lazarovits et al. (US 2002/0032486).

Regarding claim 45, Greco teaches the apparatus of claim 36 the conducting medium is saline which is a compound of water and solid NaCl dissolved in solution used to inflate the balloon. But is silent regarding wherein the inflation material is a solid medium, such as compounds including at least one substance selected from the group of: soft metals, polymers, ceramics, composites and natural materials.

Lazarovits teaches a balloon device wherein the inflation medium is liquid gas or solid or power, see [0075].

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Greco to include a solid medium as taught by Lazarovits by substituting one inflation means for another in order to inflate the balloon.

Claims 47 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 2003/0004434 A1) in view of Gregersen (WO 03/020124 A2).

Regarding claim 47 Greco teaches the apparatus according to claim 36 for drug or infusion, see [0047]. Greco is silent wherein the device, further comprising means for

passing a chemical substance through one or more channels inside the probe to a number of openings in side-walls of the probe and out into the hollow system.

Gregersen teaches a monitoring apparatus comprising means for passing a chemical substance through one or more channels inside the probe to a number of openings in side-walls of the probe and out into the hollow system (see Page 9, lines 5-30.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the apparatus taught by Greco to include chemical stimulus means as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Regarding claim 59, Greco teaches the method of claim 49. Greco is silent regarding the method wherein a measurement during thermal stimulus is performed, when the probe is filled with a fluid, preferably a liquid, the liquid introducing a change in temperature of the probe and/or balloon and thus of an outer surface of the probe and/or balloon, the outer surface being a surface abutting the inner wall of the system, and where the deformation of the system is measured in correlation with the temperature of the fluid inside the probe and/or balloon.

Gregersen teaches a method of monitoring a system wherein a measurement during thermal stimulus is performed, when the probe is filled with a fluid, preferably a liquid, the liquid introducing a change in temperature of the probe and/or balloon and thus of an outer surface of the probe and/or balloon, the outer surface being a surface abutting the inner wall of the system (introducing from an exteriorly accessible opening

of a bodily hollow system a catheter into the hollow system, said catheter being provided with an inflatable balloon situated between a proximal end and a distal end of the catheter, inflating the balloon by a fluid, preferably a liquid, until the balloon abuts the an inner wall of the hollow system in order for the balloon and the catheter to be fixed longitudinally in relation to the hollow system, introducing a thermal stimulus to the hollow system, between the exteriorly accessible opening of the hollow system and the distal end of the catheter, by means of the fluid being passed through canals inside the catheter, and maintaining a range of temperatures of the fluid in the balloon by adjusting the temperature of the fluid and passing the fluid to the balloon through one canal inside the catheter and passing the fluid from the balloon through another canal inside the catheter, and by continuously passing the fluid to and from the balloon through the canals, see at least page 8, lines 15-30 and page 15, and where the deformation of the system is measured in correlation with the temperature of the fluid inside the probe and/or balloon (see pages 2-4 and 15).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a thermal stimulus as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Regarding claims 60 and 61, Greco teaches the method of claim 49 for drug deliver. Greco is silent regarding the method apply a chemical stimulus as set forth in claims 60 and 61.

Gregersen teaches a method of monitoring a system wherein a measurement during chemical stimulus is performed, when passing of a chemical substance through a number of the canals inside the probe to a number of openings in side-walls of the probe and out into the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the composition of the chemical substance, wherein the method is performed for measuring the passage of the chemical substance past a part of the probe abutting the internal wall of the system, the passage being indicative of the ability of the system to exercise a restraining influence, alternatively to exercise a passing influence, on liquids and solids (see at least pages 3-5, pages 7 and 8-10).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a chemical stimulus as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Regarding claim 62, Greco teaches the method of claim 49. Greco is silent regarding the method wherein a measurement during an electrical stimulus is performed, when passing an electrical current through a number of wires in a number of the canals inside the probe, and when passing the electrical current to an outer surface of the probe, the outer surface being a surface abutting the inner wall of the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the magnitude of the electrical current applied.

Gregersen teaches a method of monitoring a system wherein a measurement during an electrical stimulus is performed, when passing an electrical current through a number of wires in a number of the canals inside the probe, and when passing the electrical current to an outer surface of the probe, the outer surface being a surface abutting the inner wall of the hollow system, and where the extension or the contraction of the hollow system is measured in correlation with the magnitude of the electrical current applied (see at least pages 8-10 and page 13).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Greco to include applying a electrical stimulus as taught by Gregersen in order to monitor visceral sensations to determine a level of visceral pain in a patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Form 892 for pertinent prior art not relied upon, along with additional information of the references cited in this office action.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is

(571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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